IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

UNITED STATES OF AMERICA,

Plaintiff,

v. CR-06-1362 JC

MARK E. VAN WORMER,

Defendant.

MEMORANDUM OPINION AND ORDER

THIS MATTER comes before the Court on Defendant's *Fourth Motion and Memorandum in Support Thereof to Dismiss--Agency Regulations Allow Defendant to Transfer, Possess and Use Botulinum Neurotoxins*, filed March 6, 2007 (*Doc. 35*). Having considered the Motion, the parties' submissions, the relevant authority, and being otherwise fully advised, I find the Motion not well-taken and it is denied.

I. Background

The Superceding Indictment in this matter charges Defendant Mark E.Van Wormer with frauds and swindles, alleging that Defendant, a physician, injected his patients with a substance not approved by the Federal Drug Administration (FDA), in violation of 18 U.S.C. § 1341 (Counts 1-12); misbranding a drug while held for sale, in that Defendant offered TRI-toxin for sale under the name of Botox® and Botox after the unapproved TRI-toxin was shipped in interstate commerce, in violation of 21 U.S.C. §§ 331(k) and 352(i)(3) (Count 13); and tampering with documents, namely the files of the patients he injected with the TRI-toxin, in

violation of 18 U.S.C. § 1512(c)(1) (Count 14).

These charges arise out of an investigation by FDA Miami Field Officers into the activities of Chad Livdahl, M.D., owner of a company called Toxin Research International, Inc. (TRI). TRI was distributing an unapproved drug derived from Botulinum Toxin Type A ("TRI-toxin") to certain physicians across the country, labeling the drug "For Research Purposes Only" and "Not For Human Use," but representing otherwise to the purchasers. *See* Mot., Ex. 8. While conducting a search of TRI's offices in Arizona, FDA agents learned the names of physicians who had purchased the TRI-toxin. *Id.* The Defendant's name was among them and the FDA, accordingly, began an investigation into Defendant's conduct related to his purchases of TRI-toxin.[1] Defendant presently seeks dismissal of the Superceding Indictment against him on the basis that certain agency regulations allow him, as a treating physician, to possess, use and transfer Botulinum Neurotoxins, of which Botulinum Toxin Type A ("BoNT/A") is a subspecies.

II. Legal Standard

The question for the Court on a motion to dismiss an indictment is not whether the government has presented sufficient evidence to support the charge, but solely whether the allegations in the indictment, if true, are sufficient to establish a violation of the charged offense. For the most part, that question does not involve any examination of the evidence." *United States v. Todd*, 446 F.3d 1062, 1068 (10th Cir. 2006)(citing *United States v. Sampson*, 371 U.S. 75 (1962)).

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[1]Chad Livdahl was convicted of conspiracy to commit mail fraud, wire fraud, and misbranding, and one count of mail fraud. *See* Mot., Ex. 7, *United States v. Livdahl*, case No. 05-60021-CR-COHN.

III. Discussion

In his Motion, Defendant contends that regulations implementing the Public Health Security and Bioterrorism Preparedness Act of 2002 ("Bioterrorism Act" and "Bioterrorism Regulations") authorize the conduct giving rise to the mail fraud and misbranding charges in the Superceding Indictment. Specifically, Defendant refers to the Bioterrorism Regulations' requirement that individuals and entities register with either Centers for Disease Control ("CDC") or Animal and Plant Inspection Service ("APHIS") prior to possessing, using, or transferring biological agents or toxins, such as Botulinum Toxin Type A. These Regulations state that Botulinum neurotoxins are excluded from the registration requirements if they are under the control of a treating physician and the aggregate amount does not, at any time exceed 0.5 mg. *See* 9 C.F.R. § 121.4(d)(3)' 42 C.F.R. § 73.4(d)(3). Accordingly, Defendant asserts, he was given "conflicting notices" regarding the illegal activity charged and the regulations implementing the Bioterrorism Act. This, defendant claims, violates his due process rights.

The Court agrees with the government, however, that the Bioterrorism Act and Bioterrorism Regulations are not relevant to the crimes charged for purposes of the sufficiency of the Indictment. The mail fraud charges arise out of Defendant's alleged scheme to substitute a lower-cost, non-FDA approved toxin for Allergen's more costly, approved Botox in order to enrich himself and involving the postal system. The misbranding charges similarly target deceptive practices arising from Defendant allegedly offering for sale an unapproved toxin, label "FOR RESEARCH PURPOSES ONLY," under the trademarked name of an FDA approved product, Allergan's Botox®.

Moreover, the treating physician's exclusion from the Bioterrorism Regulations relied upon by Defendant to create the purported conflict (published March 18, 2005) did not exist

when Defendant engaged in the conduct giving rise to the conduct alleged in the Superceding Indictment (January 12, 2004-November 9, 2004). Nor does Defendant address how conflicting notices, if existent, could possibly affect Count 14, which charges Defendant with tampering with documents in violation of 18 U.S.C. § 1512(c)(1). Accordingly, the Motion is denied.

WHEREFORE,

IT IS ORDERED that Defendant's *Fourth Motion and Memorandum in Support Thereof to Dismiss--Agency Regulations Allow Defendant to Transfer, Possess and Use Botulinum Neurotoxins*, filed March 6, 2007 (*Doc. 35*) is DENIED.

Dated this 19th day of April, 2007.

s/John Edwards Conway

SENIOR UNITED STATES DISTRICT JUDGE

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